Research on postoperative functioning of elderly cancer patients

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The purpose of this study is to gain experience in diagnosing Postoperative Cognitive Dysfunction (POCD) and its risk factors in surgical patients from the age of 65 years undergoing a surgical procedure for a solid malignant tumor.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26151

Bron
Nationaal Trial Register

Verkorte titel
PICNIC

Aandoening

elder patients, postoperative cognitive dysfunction, onco-geriatric, surgery

Ondersteuning

Primaire sponsor: University of Groningen
Overige ondersteuning: See sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The incidence of POCD defined by a postoperative change in cognitive function measured by the Ruff Figural Fluency score and Trailmaking test score in comparison to the preoperative

score.

Toelichting onderzoek

Achtergrond van het onderzoek

POCD is a phenomenon that has an enormous impact on the ability of elderly patients to function independently in everyday life. In this observational pilot study experience will be obtained in diagnosing POCD and its risk factors in onco-geriatric surgical patients.

Doel van het onderzoek

The purpose of this study is to gain experience in diagnosing Postoperative Cognitive Dysfunction (POCD) and its risk factors in surgical patients from the age of 65 years undergoing a surgical procedure for a solid malignant tumor.

Onderzoeksopzet

The tests will be performed at the most 1 month preoperatively and at discharge (or a maximum of 2 weeks postoperatively) and 3 months and 1 year postoperatively.
Blood and saliva samples will be obtained pre-, per- and postoperatively to determine cortisol levels as a parameter of peroperative stress and interleukin-6 levels as a parameter to determine the operative immuneresponse.

Onderzoeksproduct en/of interventie

not applicable.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Surgery is scheduled more than 24 hours after inclusion in the study as we feel this is the time necessary to obtain test results and plan the intraoperative recording of data.
- surgery under general, local or regional anesthesia.
- written informed consent given according to local regulations.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- any physical condition potentially hampering complicance with the study protocol and follo up schedule, this includes: severe visual impairment, total deafness or the inability to hold a pencil.
- personal time constraints unabling patients to comply to the study protocol.
- patients unable to comply with the outcome questionnaires (this includes insufficient knowledge of the Dutch language).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd

Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-07-2010
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-01-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4219
NTR-old	NTR4458
Ander register	METC : 2010/070

Resultaten

Samenvatting resultaten
None.